Atlas Spine, Inc.
510(k) Premarket Notification: Atlas Spine Pedicle Screw System

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510(k) Summary

Manufacturer:	Atlas Spine, Inc.
Address:	1555 Jupiter Park Drive, Suite #4 Jupiter, FL 33458
Telephone:	561-741-1108
Fax:	561-741-1870
Official Correspondent:	Jeannette G. Dailey
Title:	Vice President, Regulatory Affairs
Telephone:	561-354-4319
Device Classification Name:	Spinal pedicle fixation orthosis
Trade/Proprietary Name:	Atlas Spine Pedicle Screw System
Common Name:	Pedicle screw spinal system
Classification:	Class III per 21 CFR §888.3070
Product Codes:	MNI, MNH and NKB
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Synergy™ Spinal System Interpore Cross International K010515 Moss Miami Spinal System DePuy AcroMed, Inc. K010742 XIA® Spine System Stryker Spine K984251, K060979

OCT 19 2007

Intended Use:

The Atlas Spine Pedicle Screw System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

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Device Description:

The Atlas Spine Pedicle Screw System is a titanium alloy (6Al-4V ELI per ASTM F136) device consisting of a variety of non-sterile, single use components. The system consists of an assortment of polyaxial and monoaxial screws, cross connectors, rods, collar assemblies, offset receptacle bases and straight receptacle bases.

Equivalence to Marketed Products:

The Atlas Spine Pedicle Screw System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and material.

Performance Data:

Data were submitted to characterize the Atlas Spine Pedicle Screw System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2007

Atlas Spine, Incorporated
% Ms. Jeannette Dailey
Vice President, Regulatory Affairs
1555 Jupiter Park Drive, Suite #4
Jupiter, Florida 33458

Re: K072426
Trade/Device Name: Atlas Spine Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: August 28, 2007
Received: August 29, 2007

Dear Ms. Dailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

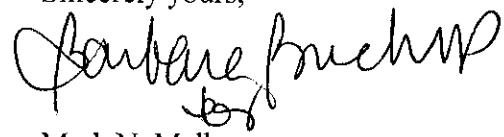
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Aot); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072426

Device Name: Atlas Spine Pedicle Screw System

Indications for Use:

The Atlas Spine Pedicle Screw System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072426